

Nguyen, Tuyen

From: Gaffin, Jeffrey
Sent: Friday, February 21, 2003 2:09 PM
To: Nguyen, Tuyen
Cc: Donovan, Lincoln; Huynh, Kim
Subject: Product by Process

2113 Product-by-Process Claims

THIS IS FOR A PROCESS LIMITATION WITHIN A PRODUCT CLAIM BUT THE CONCEPT SHOULD BE THE SAME.

PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS

~~(Even though product-by-process claims are limited by and defined by the recited process, the determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production.)~~

With regard to Claims ###, even though the claims are limited by and defined by the recited process, the determination of patentability of the product is based on the product itself, and does not depend on its method of production. If the product in the product by process claims is the same as or obvious from a product in the prior art, the claims is unpatentable even though the prior product was made by a different process *In re Thorpe*, 227 USPQ 964,966 (Fed. Cir 1985).

The limitation [*****] is a process limitation in a product claim and cannot serve to patentably define the product over the prior art of record [name of prior art applied]; See MPEP 2113 and 2173.05(p).

It is arguable that REFERENCE A does not disclose THE CLAIMED PROCESS. However, the presence of process limitations in product claims, which product does not otherwise patentably distinguish over the prior art, cannot impart patentability to that product. *In re Stephens* 145 USPQ 656 (CCPA 1965).

SEE ALSO Official Gazette dated March 26, 1996. THIS MAY BE MORE ON POINT

The court in *Ochiai and Brouwer* addressed the issue of whether an otherwise conventional process could be patented if it were limited to making or using a nonobvious product. In both cases the Federal Circuit held the use of pre rules is improper in applying the test for obviousness under 103. Rather, 103 requires a highly fact-dependent analysis involving taking the claimed subject as a whole and comparing it to the prior art. To support a rejection under 103, the collective teachings of the prior art must have suggested to one of ordinary skill in the art.... In applying this test to the claims on appeal, the Court held that there simply was no suggestion or motivation in the prior art to make or use the nonobvious products to which the claims were limited and consequently overturned the rejections based upon 103.

In light of *Ochiai and Brouwer*, Office personnel will consider all claim limitations

2173.05(p) Claim Directed to Product-By- Process or Product and Process

There are many situations where claims are permissively drafted to include a reference to more than one statutory class of invention.

I. PRODUCT-BY-PROCESS

A product-by-process claim, which is a product claim that defines the claimed product in terms of the process by which it is made, is proper. *In re Luck*, 476 F.2d 650, 177 USPQ 523 (CCPA 1973); *In re Pilkington*, 411 F.2d 1345, 162 USPQ 145 (CCPA 1969); *In re Steppan*, 394 F.2d 1013, 156 USPQ 143 (CCPA 1967). A claim to a device, apparatus, manufacture, or composition of matter may contain a reference to the process in which it is intended to be used without being objectionable under 35 U.S.C. 112, second paragraph, so long as it is clear that the claim is directed to the product and not the process.

An applicant may present claims of varying scope even if it is necessary to describe the claimed product in product-by-process terms. *Ex parte Pantzer*, 176 USPQ 141 (Bd. App. 1972).

II. PRODUCT AND PROCESS IN THE SAME CLAIM

A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph. *In Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990), a claim directed to an automatic transmission workstand and the method steps of using it was held to be ambiguous and properly rejected under 35 U.S.C. 112, second paragraph.

Such claims should also be rejected under 35 U.S.C. 101 based on the theory that the claim is directed to neither a "process" nor a "machine," but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. *Id.* at 1551

Rest of MPEP 2113

(Claim was

directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

ONCE A PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS

FOUND AND A 35 U.S.C. 102 /103 REJECTION MADE, THE BURDEN

SHIFTS TO THE APPLICANT TO SHOW AN UNOBlVIOUS DIFFERENCE

"The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) (The claims were directed to a zeolite manufactured by mixing together various inorganic materials in solution and heating the resultant gel to form a crystalline metal silicate essentially free of alkali metal. The prior art described a process of making a zeolite which, after ion exchange to remove alkali metal, appeared to be "essentially free of alkali metal." The court upheld the rejection because the applicant had not come forward with any evidence that the prior art was not "essentially free of alkali metal" and therefore a different and unobvious product.).

Ex parte Gray, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) (The prior art disclosed human nerve growth factor (b-NGF) isolated from human placental tissue. The claim was directed to b-NGF produced through genetic engineering techniques. The factor produced seemed to be substantially the same whether isolated from tissue or produced

through genetic engineering. While the applicant questioned the purity of the prior art factor, no concrete evidence of an unobvious difference was presented. The Board stated that the dispositive issue is whether the claimed factor exhibits any unexpected properties compared with the factor disclosed by the prior art. The Board further stated that the applicant should have made some comparison between the two factors to establish unexpected properties since the materials appeared to be identical or only slightly different.).

THE USE OF 35 U.S.C. 102 /103 REJECTIONS FOR PRODUCT-BY-PROCESS CLAIMS HAS BEEN APPROVED BY THE COURTS

"[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

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"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. **The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.**" In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

ONCE A PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS FOUND AND A 35 U.S.C. 102 /103 REJECTION MADE, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBlVIOUS DIFFERENCE

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